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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,498	01/10/2001	Preeti Lal	PF-0385-1 DIV	1324

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EXAMINER
SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
1644	4

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/758,498	Lal et al.
Examiner	**Art Unit**
Ron Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-20 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 10,11 are drawn to nucleic acids, classified in Class 536, subclass 23.5.

II. Claim 2 is drawn to a process for producing a protein, classified in Class 435, subclass 69.1.

III. Claims 1,5 are drawn to a polypeptide, classified in Class 530, subclass 350.

IV. Claims 16-18,20 are drawn to an antibody, classified in Class 530, subclass 387.1.

V. Claims 3,4,12,13 are drawn to a hybridization method , classified in Class 435 , subclass 6 .

VI. Claim 6 is drawn to a screening assay for an agonist, classified in Class 435, subclass 7.1.

VII. Claim 7 is drawn to a screening assay for an antagonist, classified in Class 436, subclass 501.

VIII. Claims 8,9 are drawn to a ligand screening assay, classified in Class 436, subclass 543.

IX. Claim 14 is drawn to a method of screening for altered expression of a polynucleotide, classified in Class 435, subclass 4.

X. Claim 15 is drawn for assessing toxicity, classified in Class 436, subclass 501.

XI. Claim 19 is drawn to an in vivo method of diagnosis, classified in Class 424 subclass 9.1.

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein can be made by conventional chemical synthetic methods which do not require nucleic acids or by purification of the naturally occurring protei

3. Inventions I and V or IX or X are related as product and process of use. The inventions can be

shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used to recombinantly produce the peptide which it encodes.

4. Inventions III and VI or VII or VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used as an immunogen to produce antibodies.

5. Inventions IV and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibody as claimed can be used in immunopurification procedures.

6. Inventions I,III and IV are different products. Proteins, antibodies and nucleic acids are distinct because they are structurally and functionally distinct and have different uses. The protein can be used in immunoassays to detect antibody, the antibody can be used in immunopurification methods whilst the nucleic acids can be used in nucleic acid hybridization assays. Therefore they are novel and unobvious in view of each other and are patentably distinct.

7. The nucleotides of invention I are not used in the methods of inventions VI-VIII and XI. The antibodies of invention IV are not used in the methods of inventions II, V-X. The peptides of invention II are not used in the methods of inventions II, V,IX-XI. Therefore they are novel and unobvious in view of each other and are patentably distinct.

8. Inventions II, V-XI are different methods which use different ingredients to achieve different goals. Invention II is a method of producing a protein using recombinant DNA, while invention V is drawn to a hybridization method, invention IX is drawn to a method of screening for altered expression of a polynucleotide and invention X is drawn to a method for assessing toxicity. The invention of group VI is drawn to a screening assay for an agonist, while invention VII is drawn to a screening assay for an antagonist and invention VIII is drawn to a ligand screening assay. Invention XI is drawn to an in vivo method of diagnosis which uses an antibody not used in any of the preceding methods. These methods use different ingredients and process steps to achieve different goals. Therefore they are novel and unobvious in view of each other and are patentably distinct.

9 . Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-XI is not required for any other group from Groups I-XI and Groups I-XI have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper. Therefore they are novel and unobvious in view of each other and are patentably distinct.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644